

Application Number 10/698,291

Response to Office Action mailed December 28, 2007

REMARKS

This Amendment is responsive to the Office Action dated December 28, 2007. Applicant has amended claims 18, 19, 39, 40, 50, and 51, canceled claims 6 and 27 and added claims 64-67. Claims 18, 19, 39, 40, 50, and 51 have been amended for purposes of clarification.

Claims 1-5, 7-26, and 28-67 are pending.

Claim Rejection Under 35 U.S.C. § 112

In the Office Action, claims 6 and 27 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant has deleted claims 6 and 27, thereby rendering the rejection of claims 6 and 27 moot.

Claim Rejection Under 35 U.S.C. §§ 102(e) and 103(a)

In the Office Action, claims 1, 3, 8, 9, 11-15, 20, 21, 22, 24, 29, 32-36, 41, 42, 53, 55, 58, 59, 60 and 62 were rejected under 35 U.S.C. § 102(e) as being anticipated by Falwell et al. (U.S. Patent No. 7,255,695, hereinafter "Falwell"). In addition, claims 2, 4-7, 10, 23, 25-28, 30, 31, 43-47, 52, 54, 56, 57, 61 and 63 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Falwell.

Applicant respectfully traverses the rejection. Falwell fails to disclose or suggest each and every feature of the claimed invention, as required by 35 U.S.C. §§ 102(e) and 103(a).

Independent Claims 1, 22, and 53

For example, Falwell fails to disclose or suggest a neurostimulation lead comprising a lead body, a plurality of stimulation electrodes, and a fixation mechanism including one or more wire-like elements that are expandable to fix a lead body at a target tissue site, where the fixation mechanism is mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body, the position also being axially displaced from the plurality of stimulation electrodes, as recited by Applicant's independent claim 1.

In support of the rejection of independent claim 1, the Office Action cited FIG. 14 of Falwell and characterized the braided conductive members 28B and 28C as "a plurality of

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stimulation electrodes" and the braided conductive member 28A as a fixation mechanism.¹ The conductive members 28A-2C are each made of a plurality of interlaced, electrically conductive filaments 34.² Each of the filaments 34 may form an isolated electrode or specific filaments may contact each other to form a preselected grouping.³ The Office Action appeared to rely on the fact that discrete sectors of each conductive member 28 may be activated independently, and may be activated concurrently to support the conclusion that the conductive members 28B, 28C of the Falwell catheter may be considered electrodes and the conductive member 28A may be considered an expandable fixation element that is axially displaced from the electrodes.⁴ Applicant respectfully disagrees with the Office Action's interpretation of Falwell.

Regardless of whether the electrodes defined by the conductive members 28A-28C may be activated independently or concurrently, the conductive members 28A-28C are each conductive members that define electrodes.⁵ Accordingly, if the Office Action is characterizing the conductive members 28B and 28C as stimulation electrodes, it appears that the conductive member 28A would also reasonably be considered a stimulation electrode. In this way, all of the conductive members 28A-28C shown in FIG. 14 define a plurality of electrodes, rather than a plurality of electrodes and a fixation mechanism. In contrast, Applicant's independent claim 1 recites a lead that includes a plurality of stimulation electrodes in addition to a fixation mechanism that is axially displaced from the plurality of stimulation electrodes.

Each and every claim term must be given meaning, and the claimed invention as a whole must be considered.⁶ Applicant's claim 1 clearly requires a fixation mechanism that is axially displaced from, i.e., separate from, a plurality of stimulation electrodes. Falwell does not disclose a lead that includes both a plurality of stimulation electrodes and a fixation mechanism, but rather, only discloses a plurality of conductive members that may be used to detect electrical activity during mapping procedures or to apply energy during an ablation procedure.⁷ The conductive member 28A cannot be a fixation mechanism that is axially displaced from a plurality

¹ Office Action at p. 3.

² Falwell at col. 5, ll. 60-62.

³ *Id.* at col. 6, ll. 16-21.

⁴ Office Action at p. 3, citing col. 11, ll. 63-63 of Falwell.

⁵ Falwell at col. 6, ll. 16-17.

⁶ MPEP § 2141.02.

⁷ Falwell at col. 8, ll. 1-3.

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of electrodes of the Falwell catheter, as proposed by the Office Action, because the conductive member 28A defines at least one of the electrodes.

Falwell appears to indicate that conductive member 28A does not fix the catheter 10 at a tissue site. For example, with respect to FIG. 22 of Falwell, which illustrates a catheter shaft 12 placed in an ostium of a pulmonary vein 154, Falwell states that the conductive member 28 may be expanded to its deployed position and the catheter shaft 12 may be subsequently advanced into the pulmonary vein 154. This indicates that the conductive member 28 does not fix the catheter 12 to tissue. As further support, Falwell discloses that a lubricious coating may be applied to a conductive member 28 to reduce the possibility of vascular or atrial damage.⁸ Falwell also discloses that a shroud may cover at least a portion of the conductive member 28, where the shroud may be selected such that it does "not reduce the mobility of braided conductive member 28."⁹ Accordingly, it appears that the conductive member 28 is intended to be mobile when expanded within tissue. In contrast, Applicant's independent claim 1 specifically requires the fixation mechanism to include one or more wire-like elements that are expandable to fix a lead body at a tissue target site. Accordingly, Falwell cannot disclose or suggest each and every limitation of Applicant's independent claim 1.

For at least the reasons discussed above with respect to independent claim 1, Falwell fails to anticipate Applicant's independent claims 22 and 53. Independent claim 22 recites, among other things, a plurality of stimulation electrodes disposed adjacent a distal end of a lead body and a fixation mechanism mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body, the fixation mechanism including one or more wire-like elements that are expandable to fix the lead body at a tissue target site, wherein the position is axially displaced from the plurality of stimulation electrodes. Independent claim 53 recites, among other things, a stimulation lead comprising a plurality of stimulation electrodes disposed on a lead body, and means for fixing the lead body relative to tissue proximate a tissue target site, where the fixing means includes wire-like elements that are expandable to fix the lead body at the tissue target site, the fixing means is mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body, and the position is axially displaced from

⁸ *Id.* at col. 14, l. 64 – col. 15, l. 4.

⁹ *Id.* at col. 16, ll. 46-63.

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the plurality of stimulation electrodes. Independent claim 53 has been amended to correct the antecedent basis of the recited tissue target site.

Independent Claim 42

Applicant's independent claim 42 recites a method comprising inserting a lead introducer into a patient, inserting a lead into the patient via the introducer, wherein the lead includes a lead body having a proximal end and a distal end, a plurality of stimulation electrodes disposed on the lead body, and a fixation mechanism mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body, the position being axially displaced from the plurality of stimulation electrodes and the fixation mechanism including one or more wire-like elements that are expandable to fix the lead body at a tissue target site, and removing a restraint mechanism on the fixation mechanism, thereby permitting the wire-like elements to expand. As discussed above, Falwell fails to disclose or suggest a lead that includes a fixation mechanism axially displaced from a plurality of stimulation electrodes. Accordingly, Falwell cannot disclose or suggest the method recited by Applicant's independent claim 42.

In addition, the method of independent claim 42 requires removing a restraint mechanism on the fixation mechanism, thereby permitting the wire-like elements to expand. Falwell fails to disclose a restraint mechanism that permits the conductive member 28 to expand upon removal of the restraint mechanism. Instead, Falwell discloses that movement of a sheath 26 over an inner member 22 causes a conductive member 28 to expand radially.¹⁰ Falwell also discloses that, "[a]s shaft 26 is moved distally, braided conductive member 28 emerges or everts from shaft 12."¹¹ While Falwell discloses these techniques for causing the conductive member 28 to radially expand, none of these techniques includes a restraint mechanism that is removed in order to expand the conductive member 28. Thus, Falwell cannot anticipate independent claim 42.

Dependent Claims

Claims 2-3, 7-14, 16-21, 60, and 61 depend from claim 1, claims 23, 24, 28-35, 37-41, 62, and 63 depend from claim 22, claims 43-52 depend from claim 42, and claims 53-55, 58, and 59 depend from claim 53. As established above, independent claims 1, 22, 42, and 53 are

¹⁰ *Id.* at col. 5, ll. 14-18.

¹¹ *Id.* at col. 14, ll. 26-28.

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patentable over the Falwell, and as a result, all claims depending therefrom are also patentable over Falwell. Falwell also fails to disclose or suggest the further requirements recited in dependent claims 2, 3, 7-14, 16-21, 23, 24, 28-35, 37-41, 43-55, and 58-63. Applicant addresses some of the dependent claims below for purposes of illustration.

Claims 3, 24, 45, and 55

Claims 3, 24, and 55 each recite a fixation mechanism or a means for fixing a lead body, where the fixation mechanism or fixing means includes wire-like elements each having a proximal joint where a proximal end of the respective wire-like element meets the lead body and a distal joint where a distal end of the respective wire-like element meets the lead body, and where the distal joint is weaker than the proximal joint. An example of wire-like elements including a weaker distal joint is shown in FIGS. 6A-6C of Appellant's originally filed disclosure. FIGS. 6B and 6C are copied below.

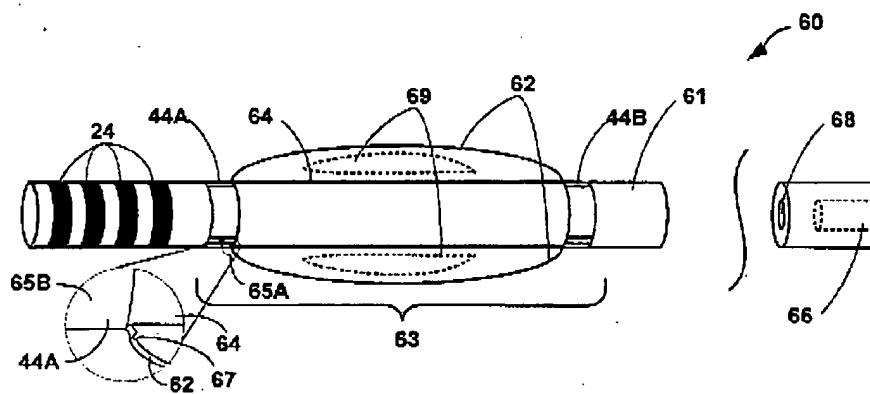


FIG. 6B

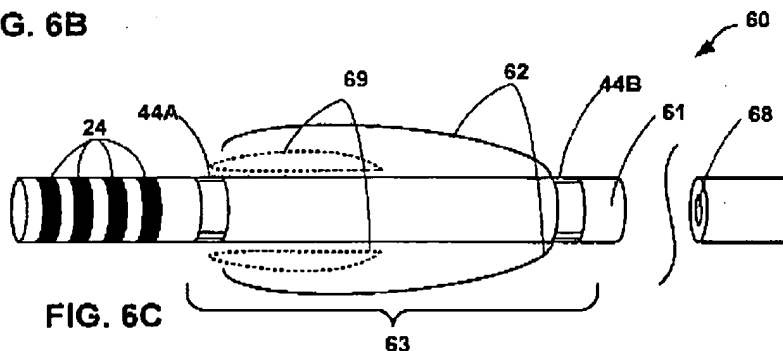


FIG. 6C

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In the FIG. 6B, the wire-like elements 62 of the fixation mechanism 63 each include a distal joint (labeled as "100" in FIG. 6B above) that is weaker than a proximal joint (labeled "102" in FIG. 6B above). As provided in Applicant's originally-filed disclosure, a weaker distal joint provides a feature that helps facilitate explantation of a lead, for example, by reducing resistance attributable to the fibrous ingrowth.¹² By promoting breakage of the distal joint during explantation of the lead, the wire-like elements of the fixation mechanism may be withdrawn around the fibrous ingrowth.¹³ Reducing resistance during lead withdrawal that is attributable to fibrous ingrowth may help minimize damage to tissue surrounding the lead during lead explantation, as well as minimize the amount of force necessary to withdraw the lead from a patient.

As an initial matter, Applicant notes that the Examiner has failed to meet the burden of illustrating how Falwell teaches or suggest the elements recited in claims 3, 24, 45, and 55. The Office Action provides no support for the conclusion that claims 3, 24, 45, and 55 are anticipated by Falwell, despite rejection claims 3, 24, 45, and 55 under 35 U.S.C. § 102(e) as being anticipated by Falwell. For example, the Office Action fails to cite to any disclosure within Falwell that demonstrates Falwell discloses wire-like elements having a proximal joint and a distal joint that is weaker than the proximal joint.

Falwell fails to disclose or suggest wire-like elements having a proximal joint and a distal joint that is weaker than the proximal joint, as required by claims 3, 24, and 55. Falwell discloses that a proximal end of a conductive member 28 is anchored to the catheter shaft 12 using an anchor band 90, and the distal end is clamped to an activating shaft using another anchor band 92.¹⁴ However, even if the conductive member 28A was a fixation mechanism, an assertion with which Applicant disagrees, Falwell does not discuss the joint strength of the filaments of the conductive member 28A, and lacks any disclosure that would have suggested the requirements of claims 3, 24, and 55.

With respect to claim 45, Falwell fails to disclose or suggest detaching a distal end of each wire-like element and withdrawing the lead from the target site. For example, Falwell does not disclose or suggest detaching a distal end of each wire-like element. Again, the Office

¹² See, e.g., Applicant's originally-filed disclosure at paragraph [0070].

¹³ See, e.g., *id.* at FIG. 6C.

¹⁴ Falwell at col. 14, ll. 19-24 and FIGS. 16A-16C.

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Action failed to point to any suggestion of such a feature in Falwell or provide any support for the rejection of claim 45.

Given the fact that Falwell clearly fails to provide any disclosure that discloses or even suggests the limitations of claims 3, 24, 45, and 55, and the lack of support provided by the Office Action for the rejection of claims 3, 24, 45, and 55, the rejection of claims 3, 24, 45, and 55 should be withdrawn.

Claims 8, 10, 29, 31, and 43

Claims 8 and 29 recite a restraint mechanism to restrain the wire-like elements of a fixation mechanism against expansion, where the wire-like elements expand upon removal of at least part of the restraint mechanism. Claims 10 and 31 depend from claims 8 and 29, respectively, and specify that the restraint mechanism includes a stylet that is accommodated by an inner lumen of the lead. Claim 43 recites a method that includes removing a restraint by withdrawing at least part of a stylet from a lumen of the lead, thereby releasing a fixation mechanism to expand. Falwell fails to disclose or suggest each and every limitation of claims 8, 10, 29, 31, and 43.

As an initial matter, Applicant respectfully submits that the Office Action failed to meet the burden of demonstrating that Falwell suggests the elements of claims 8, 10, 29, 31, and 43. For example, although the Office Action found that Falwell anticipated claims 8 and 29, the Office Action failed to provide any support for the conclusion that Falwell discloses a restraint mechanism that restrains the wire-like elements of a fixation mechanism against expansion, where the wire-like elements expand upon removal of at least part of the restraint mechanism.

In support of the rejection of claims 10, 31, and 43 as being obvious in view of Falwell, the Office Action stated that "one of ordinary skill in the art would have found it obvious to construct the shaft portion 12 with a lumen to accommodate a stylet because a stylet is an art recognized actuating device and Falwell et al suggests a thumb wheel . . . may be connected to one or more pull wires which extend through shaft portion 12 and are connected to the distal end 18 of the catheter at an off-axis location."¹⁵ However, claims 10, 31, and 43 do not merely recite a stylet. Rather, in addition to reciting that a neurostimulation lead comprises an inner lumen

¹⁵ Office Action at p. 4.

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that accommodates a stylet, claims 10 and 31 specify that the restraint mechanism that restrains the wire-like elements of a fixation mechanism against expansion comprises the stylet. Claim 43 recites a method comprising withdrawing at least part of a stylet from a lumen of the lead, thereby releasing the fixation mechanism. The Office Action appears to have disregarded these elements of claims 10, 31, and 43.

Falwell fails to disclose or even suggest the restraint mechanism recited by claims 8, 10, 29, 31, and 43. The thumb wheel that the Office Action refers to is merely used to deflect the distal end of the Falwell catheter.¹⁶ Falwell does not disclose or even suggest that actuation of the thumb wheel restrains the filaments 34 of the conductive members 28A-C. Instead, Falwell states that movement of a sheath 26 over an inner member 22 causes a conductive member 28 to expand radially.¹⁷ Thus, Falwell does not disclose or suggest a restraint mechanism that restrains wire-like elements against expansion, where the wire-like elements expand upon removal of at least part of the restraint mechanism, as required by dependent claims 8 and 29. For at least these reasons, Falwell cannot disclose or suggest a restraint mechanism that comprises a stylet, as recited by claims 10 and 31, or a method comprising withdrawing at least part of a stylet from a lumen of the lead, thereby releasing the fixation mechanism to expand, as recited by claim 43.

Even if a stylet is an "art recognized actuating device" as proposed by the Office Action, an assertion with which Applicant does not necessarily agree, the Office Action does not offer any support for the conclusion that a restraint mechanism comprising a stylet that restrains the wire-like elements of a fixation mechanism against expansion is anticipated by or obvious in view of Falwell.

Claims 11, 32, 62, and 63

Claims 11 and 32 each recite a lead including a lead body, where at least a portion of the lead body is elastic, causing a diameter of the lead body to decrease when the lead body portion is stretched. Claim 62, which depends from claim 32, recites a stylet that provides an axial force that stretches the elastic portion of the lead body to restrain the wire-like elements against expansion, and claim 63, which depends from claim 62, specifies that the elastic portion of the

¹⁶ Falwell at col. 4, ll. 61-63.

¹⁷ *Id.* at col. 5, ll. 14-18.

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lead body decreases in length upon removal of the stylet. Falwell makes no mention of an elastic lead body, much less an inner stylet that provides an axial force to stretch a lead body.

Again, the Office Action has failed to meet the burden of showing how Falwell discloses or suggest each and every element of claims 11, 32, 62, and 63. The Examiner has provided absolutely no explanation of how Falwell discloses a lead body including an elastic portion or a stylet that provides an axial force that stretches the elastic portion. The rejection of claims 11, 32, 62, and 63 is, therefore, improper and should be reversed.

For at least these reasons, the Office Action has failed to establish a prima facie case for non-patentability of Applicant's claims 1-5, 7-26, and 28-64 under 35 U.S.C. §§ 102(e) and 103(a). Reconsideration and withdrawal of the rejection of the claims is respectfully requested.

New Claims

Applicant has added claims 64-67 to the pending application. Falwell fails to disclose or suggest the inventions defined by Applicant's new claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed inventions. No new matter has been added by the new claims. Support for claims 64-66 may be found, for example, at paragraph [0043] of Applicant's originally filed disclosure and support for claim 67 may be found, for example, at paragraph [0074].

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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